REMARKS

Claim 12 has been amended to be independent and to specifically recite the limitations of base claim 1, which is hereby cancelled. The remaining claims have been amended to correctly depend from newly-independent claim 12. Claim 5 has been amended for clarity. Support for these amendments can be found throughout the specification and claims as originally filed. For example, support the amendment to claim 5 can be found in the specification at page 13, line 1 through page 14, line 5. Accordingly, no new matter has been added.

Double Patenting

The Examiner has provisionally rejected claims 1, 3-5, 7 and 10-12 on the ground of nonstatutory obviousness-type double patenting. Specifically, the Examiner asserts that claims 1, 3-5, 7 and 10-12 are allegedly anticipated by claims 1 and 5-12 of copending U.S. Application 12/682,747. As stated in the M.P.E.P.:

> If the provisional ODP rejection is the only rejection remaining in the earlier-filed of the two pending applications, (but the later-filed application is rejectable on other grounds), the examiner should then withdraw the provisional ODP rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer.

(M.P.E.P. § 1490 (V)(D)). Applicant submits that the instant application is the earlier-filed of the two copending applications. Further, as discussed below, Applicant submits the amendments to instant claims 1 and 5 overcome the rejections under 35 U.S.C. § 112, second paragraph, and 35 U.S.C. § 103(a), and as such, the provisional obviousness-type double patenting rejection is the only remaining rejection of the instant claims. Accordingly, Applicant respectfully requests that, in accordance with M.P.E.P. § 1490 (V)(D), the Examiner withdraw the provisional obviousness-type double patenting rejection.

Rejection of claims 1 and 5 under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 1 and 5 under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite. Specifically, the Examiner states that it is unclear whether the maximal length for the jelly granules recited in claim 5 refers to jelly granules prior to or after aggregation. Applicant has amended claim 5 to recite "the maximum length of ~~the~~ an individual jelly granule[[s]] measures 1 to 10 mm."

In accordance with the above, Applicant submits that the claims particularly point out and distinctly claim the subject matter of the invention. Applicant respectfully requests withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

Rejection of Claims 1, 4-9 and 11 under 35 U.S.C. § 103(a)

The Examiner has rejected claims 1, 4-8 and 11 under 35 U.S.C. § 103(a), as allegedly obvious over Nakagami et al. (WO 00/54811, hereinafter "Nakagami") in view of Fukui et al. (U.S. Patent No. 6,277,395, hereinafter "Fukui"). Further, the Examiner has rejected claim 9 under 35 U.S.C. § 103(a), as allegedly obvious over Nakagami in view of Fukui, and further in view of Yu et al. (US 2003/0064107, hereinafter "Yu"). Applicant maintains that claims 1, 4-9 and 11 are not obvious in view of the cited references. Nevertheless, solely in an effort to expedite allowance of the instant claims, Applicant has cancelled claim 1 and amended claims 2-11 to depend, either directly or indirectly, from claim 12. Applicant notes that claim 12 was not rejected over the specific combination of Nakagami in view of Fukui. Accordingly, Applicant submits that the rejection over Nakagami in view of Fukui is moot with respect to claim 1. Further, Applicant submits that because dependent claims 2-11 no longer depend from claim 1, the obviousness rejection over Nakagami in view of Fukui is no longer applicable to those claims as well.

Rejection of Claim 12 under 35 U.S.C. § 103(a)

The Examiner has rejected claim 12 under 35 U.S.C. § 103(a), as allegedly obvious over Fukui in view of Nakagami, and further in view of Gowan, Jr., et al. (US 5,374,659, hereinafter "Gowan"). Specifically, the Examiner alleges that Fukui discloses a swallowing-assistive drink that improves the swallowing of medicines, that is packaged without medicine. The Examiner concedes that Fukui does not disclose a bitterness-masking component. However, the Examiner asserts that Nakagami discloses wax substances that allegedly read on the claimed bitterness-masking component. Further, the Examiner asserts that the teachings of Gowan provide an expectation of success because Gowan allegedly teaches that a sugar alcohol can be contained in the medium surrounding the drug. The Examiner concludes that it would have been obvious to

one of ordinary skill in the art to utilize the taste masked granules of Nakagami in combination with the swallowing-assistive drink of Fukui in light of the alleged teaching of Gowan.

Applicant notes that the present technology relates to a jelly drink that facilitates taking a bitter drug and/or supplement. Specification at Abstract. Specifically, the jelly drink is packaged to be mixed by an end user with a bitter drug and/or supplement, and comprises a bitterness-masking component which provides the effect of masking bitterness when taken together with a bitter medicine and/or dietary supplement. As a blended component of the jelly drink, the bitterness-masking component is capable of binding rapidly to taste bud receptors to block binding of bitterness components to the taste bud. Specification at page 7, third full paragraph. Compared to prior art compositions that use only sugar alcohols as taste-masking components, the claimed drink shows surprisingly improved bitterness-masking properties. Thus, the claimed technology represents a significant advancement over existing swallowing-assistive beverages. As described below, Applicant submits that the instant claims are not obvious for at least the following reasons.

1) The proposed modification would render Fukui inoperable for its intended purpose.

If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). As discussed below, the proposed combination of Fukui and Nakagami would render Fukui inoperable and/or unsatisfactory for its intended purpose.

Fukui. The stated purpose of Fukui is to provide a swallowing-assistive drink that can be mixed by an end user with various medicines. The mixing can take place either in the mouth of the patient, or premixed and then poured into the patient's mouth. Fukui at column 4, lines 15-23.

Nakagami. In contrast, Nakagami discloses a manufacturing process for wax granules in which a drug is dispersed uniformly in a wax. The wax granules are designed to have very low solubility in the mouth. Nakagami at paragraph [0061]. In particular, Nakagami teaches that the wax granules are formed by melting a wax with heat, and then dispersing or dissolving the drug

therein. The resultant dispersion is then subjected to spray granulation, melting granulation, or cooling to solidification followed by crushing. Nakagami at paragraphs [0057]-[0058].

The Examiner asserts that one of skill in the art would have been motivated to use the wax granules of Nakagami to modify the swallowing-assistive drink of Fukui, because the waxes of Nakagami could be contained in the medium surrounding the drug, as allegedly evidenced by Gowan. Office Action at page 9. Applicant disagrees, and maintains that the combination of Nakagami with Fukui would render the combination inoperable or unsatisfactory for the intended purpose of Fukui.

The combination is problematic because the melting and granulation process of Nakagami would not be suitable for use in the swallowing-assistive drink of Fukui. Fukui specifically seeks a drink that can be easily mixed with a medicine by an end user, either prior to drinking or directly in the mouth of the patient. However, an end user such as a caregiver or patient would not have the necessary equipment to melt a wax, disperse a medicine in the melted wax, and then perform primary granulation of the dispersion, or cooling followed by crushing, as required by Nakagami. Additionally, the melting and granulation procedures of Nakagami are time-consuming and labor-intensive. As such, an end user seeking to mix a drink with a medicine prior to drinking (or directly in a patient's mouth) would have no motivation to perform any of the steps of Nakagami.

Furthermore, the Gowan reference fails to provide any additional disclosure that would alter the inoperability of the proposed combination discussed above. Specifically, the Examiner points to Gowan to assert that the bitter tasting medicine need not be directly coated with the taste-masking component, as in Nakagami, but rather can be contained in the medium surrounding the drug. Office Action at page 9. Although Gowan discloses sugar alcohols in an aqueous suspension, Applicant notes that such disclosure is already present in Fukui. See Fukui at column 4, lines 1-2. In contrast, Nakagami clearly distinguishes between sugar alcohols, which are "dissolved in saliva in approximately ten seconds," and the wax particles which Nakagami teaches have a "very low solubility" in the mouth. Nakagami at [0061]. Thus, although Gowan, like Fukui, discloses that sugar alcohols can be dissolved in an aqueous composition, Gowan is silent regarding any other type of taste-masking component, including wax particles. As such, there is nothing in Gowan to suggest any alternative use of the insoluble

wax particles of Nakagami. Accordingly, Gowan fails to remedy the inoperability of the proposed combination of Fukui with Nakagami.

As such, the proposed modification renders the resulting combination unsatisfactory for the intended purpose of Fukui. Accordingly, there is no suggestion or motivation to make the proposed modification to Fukui, and the claimed combination would therefore not have been obvious to one of skill in the art at the time the instant application was filed.

2) Applicant's evidence of unexpected advantages rebut any *prima facie* case by the Examiner.

Evidence of unobvious or unexpected advantageous properties can rebut *prima facie* obviousness. *See* MPEP §§ 716.02(a) and 2144.09.

In addition to the above, Applicant submits that *even if* the claimed compositions were considered *prima facie* obvious, the instant specification provides evidence of the surprising effectiveness of the claimed composition in masking the bitterness of orally-administered medicines. Specifically, the specification describes the unexpected finding that a jelly beverage comprising a bitterness-masking oil or fat is far superior to prior art compositions that lack the bitterness-masking oil or fat. The specification sets forth the results of two studies to test the superiority of the claimed compositions. The results from these studies were unexpected in view of the prior art, as discussed below.

Tables 6 and 7 set forth the results of two separate trials testing the bitterness-masking capability of the claimed composition compared to prior art compositions. When bitter medicines (i) Clarith or (ii) zithromac were combined with a composition including cacao fat and oil (Example 4), the results were surprisingly superior to a prior art composition lacking a bitterness-masking oil or fat (Comparative Example 4). Specifically, Table 6 shows that test subjects indicated the bitterness-masking effect of Example 4 as "excellent" (A) or "good" (B) within five seconds of placing the sample into the mouth. This effect is striking in comparison to the prior art composition, Comparative Example 4, which test subjects rated as "unsuitable for use" (D) and "very poor quality" (E) at the same time point.

Table 7 provides further evidence of the bitterness-masking capability of the claimed composition. Specifically, the bitter medicine Clarith was combined with either Example 4 or

any of Comparative Examples 1-4 and then analyzed using a taste sensor device. The sensor device provided a reading of bitterness on a scale of 1 to 6, with 6 being the most bitter. Specification at page 27. Strikingly, at the initial time point, Example 4 had a bitterness reading of only 1.07, compared to 4.68 for Comparative Example 4.

In summary, the results set forth in Tables 6 and 7 demonstrate that a jelly beverage comprising a bitterness-masking oil or fat is far superior to prior art compositions that lack the bitterness-masking oil or fat. These results from these studies were unexpected in view of the prior art.

Not only are these results compelling with respect to the two bitter medicines that were tested in the studies discussed above, they would also be expected to apply other bitter medicines and dietary supplements because of the drug-independent mechanism of the bitterness-masking component. As described in the specification, the bitterness-masking component is capable of binding rapidly to taste bud receptors to block binding of bitterness components to the taste bud. *See* Specification at pages 7-8. Because the bitterness-masking component binds the taste bud receptors rather than the drug or supplement, the unexpected results seen in Tables 6 and 7 would be expected in other bitter medicines and dietary supplements.

Thus, the compelling results of the tests using the claimed compounds in masking bitterness are further evidence that the claimed compounds were surprising and unexpected, and would not have been obvious to one of skill in the art. Nothing in the prior art cited by the Examiner, and nothing within the knowledge of those having skill in the art would have led one of skill in the art to the claimed compositions. Taken together, this evidence rebuts any *prima facie* case of obviousness by the Examiner.

In view of the above, Applicant submits that claim 12 is not obvious under 35 U.S.C. § 103(a). Because each of claims 2-11 depends either directly or indirectly from claim 12, Applicant also submits that none of claims 2-11 are obvious under 35 U.S.C. § 103(a). Applicant respectfully requests withdrawal of this rejection and allowance of the pending claims.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending application of the present application's assignee.

Serial No.	Title	Filed
12/682,747	GRANULAR JELLY BEVERAGE FOR MEDICATION AND PROCESS FOR PRODUCING THE SAME	10/12/07

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: September 12, 2011

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